

Applicant: Jay M. Short  
Application No.: 09/421,629  
Filed: October 19, 1999  
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47. (Twice Amended) The method of claim 32 which comprises both the steps of  
(i) amplifying the cDNA or genomic DNA fragments and (ii) recovering a fraction of the cDNA  
or genomic DNA fragments having a desired characteristic.

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**REMARKS**

Claims 32-47 were pending before this Response. By the present communication paragraph 1 of page 1 of the application has been amended to revise the priority data. In addition, claims 32 and 44-47 have been amended to claim Applicant's invention with greater particularity. No claims have been cancelled or added. The amendments add no new matter, the amended claim language being fully supported by the specification and original claims. Applicant submits that the claim amendments do not narrow the claims in any way within the meaning of Festo Corporation v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd., a/k/a SMC Corporation and SMC Pneumatics, Inc. 234 F.3d 558, 51 U.S.P.Q. 2d 1959 (Fed. Cir. 2000). Accordingly, claims 32-47 are currently pending.

**The objection to the continuity data**

The Office Action objects to the amended continuity data filed January 3, 2002 on the grounds that it is confusing. With regard to the recitation of copendency, the Examiner advises that there is no copendency between the instant application filed October 19, 1999, and the 08/657,409 application, which issued on September 28, 1999. Accordingly, as suggested by the Examiner, the continuity data in paragraph 1 of the application has been amended to recite:

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This application is a continuation application of U.S. Patent Application Serial No. 08/988,224, filed December 10, 1997, now issued as U.S. Patent No. 6, 280,926, which is a continuation application of U.S. Patent Application Serial No. 08/657,409, ..."

The Office Action further asserts that the present application is not a continuation or divisional of application Serial No. 09/089,789 because the present application as well as 08/988,224 and 08/657,409 are different applications than 09/089,789 and Applicant has indicated that the present application is identical to Serial No. 08/988,224 (Office Action, page 2). Accordingly, Applicant has further amended the continuity data in paragraph 1 of the application to remove reliance upon Serial No. 09/089,789.

In view of these amendments to the continuity data, Applicants respectfully submit that the recitation of the continuity data in paragraph 1 of the application is correct and reconsideration and withdrawal of the objection are respectfully requested.

#### **The Declaration**

The Office Action asserts that the Declaration of record is defective for failing to comply with 37 C.F.R. § 1.37 and requests submission of a new Declaration in which the priority information is corrected. Applicant submits herewith a new unsigned Declaration that recites the priority information as contained in the amended paragraph 1 of the application. The signed Declaration will be submitted as soon as an executed copy is available. Applicant respectfully

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submits that the new Declaration is in full conformance with 37 C.F.R. § 1.37 and reconsideration and withdrawal of the objection to the declaration are respectfully requested.

**The Rejection Under 35 U.S.C. § 112. First Paragraph**

Applicant traverses the rejection of claims 32-47 under 35 U.S.C. § 112, First Paragraph, as allegedly lacking an enabling written description in the Specification (as set forth in Paper No. 12 herein). In particular, Applicant disagrees with the Examiner's assertion:

While it is possible to identify a gene encoding a single enzyme by the claimed method, the identification of a metabolic pathway or gene cluster is a different matter.

(Office Action, page 3). The present claims recite that what is "identified" by the invention method is "a vector containing an expression construct that produces the bioactivity or biomolecule of interest encoded by the cDNA or genomic DNA fragments in the library," not specifically the gene cluster or metabolic pathway, which could be interpreted to mean that the gene cluster or metabolic pathway was isolated. The Examiner acknowledges in the Office Action that enablement for claims drawn to a gene expression library that contains partial or complete metabolic pathways is provided by a priority document having a date of June 3, 1996 (Office Action, page 3) (i.e., by parent application Serial No. 08/657,409).

In addition, the present claims have been amended to delete subject matter pertaining to normalization of libraries so that the present claims do not rely for description or enablement on

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applications 09/089,789, 09/034,724, and 08/665,565, which the Examiner asserts would constitute introduction of new matter if relied upon for priority.

Therefore, with regard to amended claims 32-47, from which reference to "normalizing" and a "normalized" library as well as amplifying the "copy number" has been deleted, Applicants submit that an enabling disclosure is provided by the present Specification and the priority documents set forth in the amended continuity data in paragraph 1 of the application, which have been incorporated by reference into the application. A reconsideration and withdrawal of the rejection of claim 32-47 under 47 under 35 U.S.C. § 112, First Paragraph, as allegedly lacking an enabling written description in the Specification are respectfully requested.

#### **The Rejection under 35 U.S.C. § 112, Second Paragraph**

Applicant respectfully traverses the rejection of claims 32-47 under 35 U.S.C. § 112, Second Paragraph, as being indefinite due to the term "in the normalized library" in claim 12 allegedly being confusing. In support of the rejection, the Examiner asserts that the phrase at issue is allegedly "not defined in the Specification" so that those of skill in the art would not know the metes and bounds of the claim. However, amended claim 32 does not contain the phrase "normalized library" or the term "normalizing." Accordingly, Applicant respectfully submits that the rejection is moot and present claims 32-47 meet all requirements under 35 U.S.C. § 112, Second Paragraph. Therefore, reconsideration and withdrawal of the rejection are respectfully requested.

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In view of the above amendments and remarks, reconsideration and favorable action on claims 32-47 are respectfully requested. If the Examiner would like to discuss any of the issues raised in the Office Action, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,

Date: May 15, 2002



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Enclosure: Exhibit A  
New Declaration

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Exhibit A: Page 1

**EXHIBIT A**

**Version with Markings to Show Changes Made**

**In the Specification:**

Please amend Paragraph 1 on page 1 as follows:

This application is a continuation application of U.S. Patent Application Serial No. 08/988,224, filed December 10, 1997, now issued as U.S. Patent No. 6, 280,926, which is a continuation application of U.S. Patent Application Serial No. 08/657,409, which was filed on June 3, 1996, now issued as U.S. Patent 5,958,672; which was a continuation-in-part of U.S. application Serial No. 08/568,994 which was filed on December 7, 1995, now abandoned; which is a continuation-in-part of U.S. application Serial No. 08/503,606 which was filed on July 18, 1995, now issued as U.S. Patent 6,004,788; and a continuation application of U.S. Patent Application Serial No. 09/089,789, filed June 3, 1998, pending; which is a continuation-in-part application of U.S. Patent Application Serial No. 09/034,724, filed March 4, 1998, now issued as U.S. Patent No. 6,001,574; which is a continuation-in-part application of U.S. Patent Application Serial No. 08/665,565, filed June 18, 1996, now issued as U. S. Patent No. 5,763,239], each of which is incorporated herein by reference in its entirety.

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**In the Claims**

Please amend claims 32 and 44-47 as follows:

32. (Twice Amended) A method for identifying a bioactivity or biomolecule of interest comprising:

a) culturing a gene expression library comprising a pool of expression constructs, each expression construct comprising a vector containing one or more cDNA or genomic DNA fragments, wherein the cDNA or genomic DNA fragments in the pool of expression constructs are derived from a plurality of species of donor organisms[, wherein the library is formed by normalizing the representation of various DNAs within the cDNA or genomic DNA fragments so as to form a normalized library of cDNA or genomic DNA fragments]; and

b) identifying a vector containing an expression construct that produces the bioactivity or biomolecule of interest encoded by the cDNA or genomic DNA fragments in the [normalized] library.

44. (Twice Amended) The method of claim [32] 45 which comprises the step of amplifying the [copy number of] the cDNA or genomic DNA fragments.

45. (Twice Amended) The method of claim [32] 45 wherein the step of amplifying the DNA precedes the [normalizing] identifying step.

46. (Twice Amended) The method of claim 32 wherein the identifying step [of normalizing the DNA] precedes the amplifying step.

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47. (Twice Amended) The method of claim 32 which comprises both the steps of (i) amplifying [the copy number of] the cDNA or genomic DNA fragments and (ii) recovering a fraction of the cDNA or genomic DNA fragments having a desired characteristic.